K071764

# 510(k) Summary

OCT 2 4 2007

**Company** Obtech Medical Sarl
Chemin-Blanc
LeLocle, Switzerland CH-2400

**Contact** Elizabeth Miller
Regulatory Affairs Associate II
Ethicon Endo-Surgery, Inc.
4545 Creek Road
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**Date Prepared** June 28, 2007

**Device Name** Trade Name: REALIZE™ Gastric Calibration Tube
Common or Usual Name: Gastrointestinal Tubes
Classification Name: Tubes, Gastrointestinal (And Accessories)
[21 CFR 876.5980 (KNT)]

**Predicate Device** COOK® Gastric Sizing Balloon Catheter
BioEnterics® Gastric Balloon Suction Catheter

**Device Description** The REALIZE™ Gastric Calibration Tube is a non-sterile, single patient use instrument consisting of a 745 mm long silicone tube with an approximate 38 F (12.7mm) rounded, closed tip. At the proximal end, the tube is equipped with a check valve which mates with a syringe used to fill a balloon located approximately 6.8 cm from the distal tip. At the distal end, the tube has two suction/irrigation holes that allow the removal of fluids and/ or irrigation during the procedure, if necessary. Reference markings are provided on the tube shaft, with the zero reference located approximately 39.6 cm from the proximal end of the balloon.

**Indications for Use** The gastric calibration tube is indicated for use in gastric and bariatric surgical procedures to provide visible and tactile delineation of the antrum of the stomach along with the ability to decompress the stomach, drain and remove gastric fluid and size a gastric pouch.

**Technological Characteristics** The REALIZE™ Gastric Calibration Tube is similar to the design, function and materials of the predicate devices BioEnterics® Gastric Balloon Suction Catheter and COOK Gastric Sizing Balloon Catheter. The REALIZE™ Gastric Calibration Tube has the same indications for use as the predicates.

**Performance Data** Bench testing was performed to evaluate the performance of the intended use of the new device. The performance testing shows that the REALIZE™ Gastric Calibration Tube is equivalent to the BioEnterics® Gastric Balloon Suction Catheter.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 24 2007

Obtech Medical Sarl
c/o Linda G. Hill, RAC
Group Manager, Regulatory Affairs
Ethicon Endo-Surgery, Inc.
4545 Creek Road
CINCINNATI OH 45242

Re: K071764
Trade/Device Name: REALIZE™ Gastric Calibration Tube
Regulation Number: 21 CFR §876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: II
Product Code: KNT
Dated: August 11, 2007
Received: September 12, 2007

Dear Ms. Hill:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

| | | |
|---|---|---|
| 21 CFR 876.xxxx | (Gastroenterology/Renal/Urology) | 240-276-0115 |
| 21 CFR 884.xxxx | (Obstetrics/Gynecology) | 240-276-0115 |
| 21 CFR 892.xxxx | (Radiology) | 240-276-0120 |
| Other | | 240-276-0100 |

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K071764

Device Name: **REALIZE™ Gastric Calibration Tube**

Indications for Use:

The gastric calibration tube is indicated for use in gastric and bariatric surgical procedures to provide visible and tactile delineation of the antrum of the stomach along with the ability to decompress the stomach, drain and remove gastric fluid and size a gastric pouch.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)



*(Posted November 13, 2003)*

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K071764